SEP - 3 2003

K032012

DIAZYME

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SUMMARY

Submitter's name:	Diazyme Laboratories
Address:	3550 General Atomics Ct.
Phone:	858-455-4754
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Name of contact person:	Greg Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821
Date the summary was prepared:	June 18, 2003
Name of the device:	Homocysteine Microtiter Plate Assay
Trade or proprietary name:	Homocysteine Microplate HPB Assay
Common or usual name:	Homocysteine Microtiter Plate Assay
Classification name:	Single (specified analyte controls (per 21 CFR section 862.1660)

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

Axis Homocysteine EIA, manufactured by Axis Biochemicals, AS. The clearance number is K980907.

Description of the device:

Homocysteine Microplate HPB Assay is an EIA-like assay for the determination of tHcy (L-homocysteine) in blood. The assay employs a genetically engineered Homocysteine Binding Protein (HBP) as the capturing reagent. Plasma samples are pretreated in vials with a reducing agent, TCEP, to reduce the protein bound Hcy to free Hcy that is subsequently converted to S-adenosyl-L-homocysteine (SAH) by SAH hydrolase and quantitated by the HBP in a competition assay between free SAH from samples and tracer SAH-HRP conjugate.

Intended use of the device:

The Homocysteine Microtiter Plate Assay is intended for the quantitative determination of total L-homocysteine in human serum or plasma.

The device can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

Summary of the technological characteristics of our device compared to the predicate device:

The Diazyme Homocysteine Microtiter Plate Assay and the Axis Homocysteine EIA have similar technological characteristics and have been shown to be substantial equivalent.

The following areas were evaluated and shown to be substantially equivalent comparisons to the predicate:

Indications for Use
Methodology
Test Objective
Type of Test
Specimen Type
Product Type
Reagents
Performance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Diazyme Laboratories
c/o Mr. Greg Holland
Regulatory Specialists, Inc.
3722 Avenue Sausalito
Irvine, CA 92606

Re: k032012
Trade/Device Name: Homocysteine Microtiter Plate Assay
Regulation Number: 21 CFR 862.1377
Regulation Name: Single (specified) analyte controls
Regulatory Class: Class II
Product Code: LPS; JJX
Dated: June 27, 2003
Received: July 2, 2003

Dear Mr. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032012

Device Name: Homocysteine Microtiter Plate Assay

Indications For Use:

The Homocysteine Microtiter Plate Assay is intended for the quantitative determination of total L-homocysteine in human serum or plasma.

The device can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off for Sean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032012

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109) (Optional Format 1-2-96)